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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,052	09/28/2000	Michael K. Skinner	252/124	9790

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EXAMINER	
WHISENANT, ETHAN C	
ART UNIT	**PAPER NUMBER**
1634	10

DATE MAILED: 07/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/676,052	Applicant(s) SKINNER ET AL.	
	Examiner Ethan C. Whisenant	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. The applicant's response (filed 15 MAY 02) has been entered. The applicant's response has been entered as paper no. 9. The claims pending in this application are Claim(s) 1-21 with Claims 1-16 withdrawn as the result of a restriction requirement, leaving **Claims 17-21** under examination. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 102/103

5. **Claim(s) 17** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DeRisi et al. (DEC 1996).

Claim 17 is drawn to a physical platform comprising an array of nucleic acid polymers immobilized at predetermined positions on a solid support wherein the array comprises at least two different nucleic acid polymers each of which are specific for a different gene associated with lipid metabolism, synthesis or action. In addition the array is to comprise genomic DNA derived from a patient tissue sample that comprises a label.

DeRisi et al teach an array of nucleic acid polymers comprising all of the limitations recited in Claim 17 except these authors do not teach that the at least two different nucleic acid polymers should be specific genes associated with lipid metabolism, synthesis or action. Admittedly, DeRisi et al. do not teach that the genomic DNA used on their arrays is derived from patient samples (see figure 1, total human – also note that the total human DNA in figure 1 is labeled with YOYO, a DNA specific fluorescent dye), however, it is well established that a product is not limited by the why it is made but rather by its structure. If the product in a claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

CLAIM REJECTIONS UNDER 35 USC § 103

6. **Claim(s) 18-20** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over DeRisi et al. (DEC 1996) in view of Gao et al. (1994) and/or Fukushima et al. (FEB 1993 - Abstract only) and/or Goetzl et al. (SEP 1999 - Abstract only) and/or Haapamski et al. (MAR 1999 - Abstract only) and/or Gibbs et al. (SEP 1999 - Abstract only) and/or Lockhart et al. (1996).

Claim 18 is drawn to an embodiment of Claim 17 wherein the at least two different nucleic acid polymers which are specific for a different gene associated with lipid metabolism, synthesis or action are selected from a defined group which includes Phospholipase A2, Phospholipase D1, and EDG 2.

DeRisi et al teach an array of nucleic acid polymers comprising all of the limitations recited in Claim 18 except these authors do not explicitly teach that the at least two different nucleic acid polymers which are specific for a different gene associated with lipid metabolism, synthesis or action are selected from a defined group which includes Phospholipase A2, Phospholipase D1, and EDG 2. However, Gao et al. do teach that genes expressed in lipid metabolism pathways play a critical role in metastasis. Fukushima et al. teach measuring the level of mRNAs associated with lipid metabolism, synthesis or action in normal, diseased, and regenerating liver. Goetzl et al. teach detecting mRNAs for Edg-1, Edg-2, Edg-3, Edg-4, Edg-5 while Haapamski et al. teach detecting mRNAs for phospholipase A2. Finally, Gibbs et al. teach detecting mRNAs for phospholipase D1. In view of the cumulative teachings in the prior art, and absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the array(s) taught by DeRisi et al. wherein the array comprises nucleic acid polymers which are specific for Phospholipase A2, Phospholipase D1, Edg-1, Edg-2, Edg-3, Edg-4, and Edg-5. The ordinary artisan would have been motivated to modify the array of DeRisi et al. in order to analyze the expression pattern of said genes in human cancer in the most expeditious way possible - that at the time of the invention being the array methodology taught by DeRisi et al.

Furthermore, it is examiners position, that absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to add any **known** gene (i.e. cDNA or EST) to an array of known genes/ESTs in order to analyze the differential gene expression patterns in different tissues/cancer. For motivation to make this modification see, for example, DeRisi et al., the last two paragraphs on page 458 . Also note Lockhart et al. (1996) page 1679, Column 1 beginning at about line 18. As all of the genes recited in Claim 18 were known it would appear to the examiner there was more than ample teachings in the prior to motivate the ordinary artisan to add any **known** gene (i.e. cDNA or EST) to arrays of known genes/ESTs in order to analyze the differential gene expression patterns in different tissues/cancer.

Claim 19 is drawn to an embodiment of Claim 19 wherein one of the at least two different nucleic acid polymers which are specific for a different gene associated with lipid metabolism, synthesis or action is selected from a defined group which includes Phospholipase A2, Phospholipase D1, and EDG 2.

As argued above, DeRisi et al. (DEC 1996) in view of Gao et al. (1994) and/or Fukushima et al. (FEB 1993 - Abstract only) and/or Goetzl et al. (SEP 1999 - Abstract only) and/or Haapamski et al. (MAR 1999 - Abstract only) and/or Gibbs et al. (SEP 1999 - Abstract only) reasonably suggest (i.e. make prima facie obvious) this embodiment.

Claim 20 is drawn to an embodiment of Claim 17 wherein at least one of the nucleic acid polymers specific for the selected genes is a nucleic acid polymer comprising at least about 19 nucleotides.

DeRisi et al. teach this limitation wherein these authors teach that "the arrays used contain either 16,000 or more than 65,000 different 20-mer oligonucleotides of defined sequence ..." See p. 1675, 1st column, 1st paragraph.

7. **Claim(s) 21** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over DeRisi et al. (DEC 1996) as applied above and further in view of Bovenberg et al.[US 5,747,285 (1998)].

Claim 21 is drawn to an embodiment of Claim 17 wherein at least one of the nucleic acid polymers specific for the selected genes is a nucleic acid polymer comprising at least about 19 nucleotides and will hybridize to a non-coding sequence functionally linked to the coding region of one of the selected genes wherein said functionally linked non-coding sequence is unique to that gene.

Admittedly, DeRisi et al. do not explicitly teach the limitation wherein the selected genes is a nucleic acid polymer which hybridizes to a non-coding region functionally linked to one of the selected genes wherein the functionally linked sequence is unique to said gene. However, it was well known at the time of the invention that one could detect a target polynucleotide by hybridizing to a non-coding region of said target polynucleotide as long as said region was specific for said target. see for example Bovenberg et al.[US 5,747,285 (1998)]. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan in the art at the time of the invention that one could with a reasonable expectation of success hybridize to a non-coding sequence functionally linked to the coding region of one of the selected genes as long as the functionally linked sequence is unique to said gene. Motivation for modifying the array of DeRisi et al. comes from expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Absent an unexpected result, the substitution of one well known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

8. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection however, the examiner would like to address at least one point. The applicant argues that the invention relates to the detection of copy number of a particular gene and not to measuring the expression of a particular gene. In response the examiner respectfully points out that the invention being claimed is drawn to a product (i.e. a physical platform comprising an array). It is well established that a product is not limited by the why it is made but rather by its structure. If the product in a claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In addition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963); *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

The applicant also argues that Chee et al. do not teach measuring the copy number of a gene. In response the examiner readily admits that Chee et al. do not teach measuring the copy of a gene. However, it was well known in the art at the time of the invention that one could with a reasonable expectation of success use arrays to measure the copy number of a particular gene, see for example Bao et al [US 6,251,601(2001)].

CONCLUSION

9. **Claim(s) 17-21** is/are rejected and/or objected to for the reason(s) set forth above.

10. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Art Unit is (703) 308-8724. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

ETHAN C. WHISENANT
PRIMARY EXAMINER